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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,372	07/24/2003	Harrihar A. Pershadsingh	421842000400	2447

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT PAPER NUMBER

1614

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/627,372	PERSHADSINGH, HARRIHAR A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9, 10, 12, 14, 15 and 19-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10, 12, 14, 15 and 19-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

*Handwritten signature/initials*

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Claims 1-7, 9, 10, 12, 14, 15 and 18-32 are presented for examination.

Applicants' amendment filed April 6, 2005 has been received and entered.

Accordingly, the rejections made under 35 USC 112, second paragraph and 35 USC 103 as set forth in the previous Office action dated January 26, 2005 at pages 7, 9 and 10 are hereby withdrawn.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9, 10, 12, 14, 15 and 18-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 58-87 of copending Application No. 10/801,437. Although the conflicting claims are not identical, they are not patentably distinct from each other because present application teaches a method for treating or prophylactically preventing an inflammatory or metabolic disorder in a mammal by administering to the mammal in need thereof, a therapeutically effective amount of a compound,

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irbesartan or telmisatran, sufficient to (a) at least partially activate peroxisome proliferators activated receptors (PPARs) and (b) at least partially inhibit, antagonize or block an activity of angiotensin II type 1 receptors; and the copending application teaches a method for treating or preventing an inflammatory or metabolic disorder in a mammal comprising administering to the mammal in need of thereof, a therapeutically effective amount of a compound sufficient to at least partially activate a peroxisome proliferators-activated receptor (PPAR). The claims of the copending application, 10/801,437, teaches the limitations of the claims of the present application since the instant compound known to at least partially activate a (PPAR) would inherently at least partially inhibit, antagonize or block an activity of angiotensin II type 1 receptor and is the only compound(s) known to possess the said two steps mechanisms as suggested by the applicants' specification of copending application 10/801,437 on page 2, page 0005.

The rejection made under a provisional obviousness-type double patenting is adhered to.

Claims 1-7, 9, 10, 12, 14, 15 and 18-32 are not allowed.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1-7, 9, 10, 12, 14, 15 and 18-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating type-2 diabetes, metabolic syndrome and inflammation caused by osteoarthritis with telmisartan, does not reasonably provide enablement for treating all inflammatory or metabolic disorders or prophylactically preventing an inflammatory or metabolic disorder by administering all compounds, including irbesartan, sufficient to least partially activate peroxisome proliferators activated receptors (PPARs) and at least partially inhibit, antagonize or block an activity of angiotensin II type 1 receptors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

As of record, for reasons of record as set forth in the Office action dated January 26, 2005 at pages 3-6 as applied to claims 1-15.

Again, applicants' specification does not provided any test results or working examples showing telmisartan will, in fact, prevent inflammatory or metabolic disorders in a healthy mammal that does not have any inflammatory or metabolic disorders. By administering the telmisartan to this healthy mammal, it will not get an inflammatory or metabolic disorder during its lifetime.

Applicants' results show the mammal had the disorder or presently has it, thus the administering of telmisartan prevents the mammal from having a reoccurrence of the disorder.

Again, applicants' specification does not any test results or experimental data showing the administration of irbesartan will treat or prevent inflammatory or metabolic disorders.

The rejection made under 35 USC 112, first paragraph is adhered to.

Claims 1-7, 9, 10, 12, 14, 15 and 18-32 are not allowed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-32 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Donnell et al., "Irbesartan lowers blood pressure and ameliorates renal injury in experimental non-insulin-dependent diabetes mellitus", *Kidney International*, Vo. 52, Supplement 63, (1997), pages S218-S220, of record, for reason of record as set forth in the previous Office action dated January 26, 2005 at pages 7 and 8 as applied to claims 1, 3-17, 13 and 14.

O'Donnell et al. teach the use of irbesartan, a compound that partially activated peroxisome proliferators activated receptors (PPARs) and partially inhibit, antagonize or block an activity of angiotensin II type 1 receptor, to low blood pressure and ameliorates renal injury in experimental non-insulin-dependent diabetes mellitus (a metabolic disorder). (See the abstract) Note particularly lines 6-8 shown irbesartan was administered in the drinking water (orally) in a dosage range of 15 mg to 50 mg in which the applicants' preferred dosage range of about 20 mg to about 1000 mg overlaps. As to the irbesartan increases the activity of a PPAR subtype, PPARgamma or a PPARgamma-retinoid X receptor heterodimer is inherent since a compound of identical function cannot have mutually exclusive

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properties. If the prior art teaches the identical compound (a compound of claim 19), the properties applicant discloses and/or claim is necessarily present. (See In re Spada, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir., 1990)). Clearly, the cited reference anticipates the applicants' instant invention, therefore, the instant invention is unpatentable.

Claims 19-32 are not allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

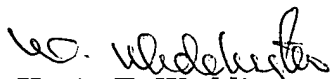
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

K. Weddington  
June 26, 2005